UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,602	11/14/2005	Peter H. Breen	UCIVN-024US	7181

33197 7590 06/03/2009

STOUT, UXA, BUYAN & MULLINS LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

EXAMINER	
DIXON, ANNETTE FREDRICKA	
ART UNIT	**PAPER NUMBER**
3771	

MAIL DATE	DELIVERY MODE
06/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,602	BREEN, PETER H.	
	Examiner	Art Unit	
	Annette F. Dixon	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 24-35* is/are rejected.

7)☒ Claim(s) *23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 April 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Examiner acknowledges claims 1-35 are pending in this application.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be "material to patentability as defined in 37 CFR 1.56."

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: for example: circle vent circuit (10) and open vent circuit (10').

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: for example: reference character 52 and reference character 17.

6. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 5, 7, 8, 11-21, 25-29, and 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Heinonen (6,196,222).

As to Claim 1, Heinonen discloses a bymixer device that is connectable to a respiratory gas flow conduit in a ventilation circuit (Figure 3) used for ventilating a human or veterinary patent, said bymixer device comprising: a flow divider (the point at which the inlet flow on conduit 40 is divides to conduit 56) for dividing the flow of respiratory gas into first and second streams; a main flow channel (conduit 40 to 44) thought which the first stream flows; a bypass flow channel (conduits 56 to conduit 58 to conduit 44) through which the second stream flows; said bypass flow channel, comprising: a) a flow restrictor (76) that restricts the flow of gas through the bypass flow conduit, b) a mixing chamber (74) positioned upstream of the flow restrictor (84), and c) sampling apparatus (82) for sampling respiratory gas from said mixing chamber (74) (Column 8, Lines 38-50). Regarding the flow restrictor, a valve is a type of flow restrictor. Regarding the sampling apparatus, Applicant has not recited within the claim language the specific type of sampling (pressure, flow, concentrations of gas) required, thus as the pressure sensor (82) is utilized to monitor the pressure within the conduit after the mixing chamber (74) it meets the claim language.

As to Claim 2, Heinonen discloses a flow combiner (68) that is connectable to the main flow channel (conduit 40 to 44) and the bypass channel (conduits 56 to conduit 58 to conduit 44) and operative to combine the first and second streams after they have passed through the main flow channel and the bypass channel. (Column 7, Lines 14-20 and Column 8, Lines 60-67).

As to Claim 3, Heinonen discloses the size of the mixing chamber (74) is variable (Column 8, Lines 20-23).

As to Claim 5, Heinonen discloses the flow restrictor (76) is variable (as controlled by the controller) (Column 8, Lines 23-38).

As to Claim 7, Heinonen discloses the sampling apparatus (82) is connected to the bypass flow channel (conduits 56 to conduit 58 to conduit 44) for sampling respiratory gas from said mixing chamber (74) (Column 8, Lines 38-50).

As to Claims 8 and 11, Heinonen discloses the sampling apparatus (82) is connected to the control unit (60) and may be monitored and displayed with the user interface (62). (Column 8, Lines 51-60).

As to Claims 12-14, Heinonen disclose the controller (60) controls the loading of the mixing chamber (74) by regulating the pressure, flow, and volume of gas delivered. (Column 8, Lines 38-50). Inherently, to be able to perform this function, the controller (60) was programmed at fabrication and is a microprocessor capable of making determinations of the device's operational status.

As to Claim 15 and 33, Heinonen disclose the determination of the tidal volume, and respiration rate over time. (Column 3, Lines 7-67).

As to Claim 16, please see the rejection of claim 1. The difference between claim 16 and the rejection of claim 1 is the incorporation the particulars of the ventilation circuit. Specifically, Heinonen disclose an inspiratory flow conduit which carries a flow of inspiratory respiratory gas for delivery into the patient's lungs (from the ventilator 10 to conduits 40-46-44-68, trachea 48 and lungs 50), an expiratory flow circuit for carrying expired respiratory gas that has been expired from the lungs (from the lungs 50 to

trachea 48, conduits 68-44-46-42, and the ventilator 10), where the bymixer of claim 1 is connected to the inspiratory flow conduit, as defined.

As to Claim 17, please see the rejection of claim 16. The difference between claim 17 and the rejection of claim 16 is the limitation of the ventilation circuit is an open circuit (Figure 3).

As to Claim 18, Heinonen discloses the ventilation circuit may be closed. (Column 9, Lines 15-45 and Figure 4).

As to Claim 19, Heinonen discloses the use of a carbon dioxide absorber (100). (Figure 4).

As to Claim 20, Heinonen discloses fresh gas (106) is inserted into the closed circuit system after the recycled gas has been absorbed of carbon dioxide. (Figure 4).

As to Claim 21, Heinonen discloses the sampling apparatus (82) is connected to the bypass flow channel (conduits 56 to conduit 58 to conduit 44) for sampling respiratory gas from said mixing chamber (74) (Column 8, Lines 38-50).

As to Claim 25, please see the rejection of claim 1. The difference between claim 25 and the rejection of claim 1 is the incorporation the particulars of the ventilation circuit. Specifically, Heinonen disclose an inspiratory flow conduit which carries a flow of inspiratory respiratory gas for delivery into the patient's lungs (from the ventilator 10 to conduits 40-46-44-68, trachea 48 and lungs 50), an expiratory flow circuit for carrying expired respiratory gas that has been expired from the lungs (from the lungs 50 to trachea 48, conduits 68-44-46-42, and the ventilator 10), where the bymixer of claim 1 is connected to the inspiratory flow conduit, as defined.

As to Claim 26-29, Heinonen discloses the sampling apparatus (82) is connected to the bypass flow channel (conduits 56 to conduit 58 to conduit 44) for sampling respiratory gas from said mixing chamber (74), where the variable is the pressure within the mixer (Column 8, Lines 38-50).

As to Claim 34, Heinonen discloses the size of the mixing chamber (74) is variable (Column 8, Lines 20-23).

As to Claim 35, Heinonen discloses the flow restrictor (76) is variable (as controlled by the controller) (Column 8, Lines 23-38).

9. Claims 1-3, 5, and 7-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Cutler et al. (4,619,269).

As to Claim 1, Cutler discloses a bymixer device that is connectable to a respiratory gas flow conduit in a ventilation circuit (Figures 2 and 3) used for ventilating a human or veterinary patent, said bymixer device comprising: a flow divider (the point at which conduit 12 meets conduit 13 and conduit 21) for dividing the flow of respiratory gas into first and second streams; a main flow channel (21) thought which the first stream flows; a bypass flow channel (conduits 13-28-38) through which the second stream flows; said bypass flow channel, comprising: a) a flow restrictor (30) that restricts the flow of gas through the bypass flow conduit, b) a mixing chamber (32) positioned upstream of the flow restrictor (30), and c) sampling apparatus (sensors 33, 48 or 52) for sampling respiratory gas from said mixing chamber (32) (Figure 3). Regarding the flow restrictor, a valve is a type of flow restrictor. Regarding the limitation of “restricts

the flow of gas through the bypass flow conduit", the device of Cutler divides a portion of the flow and restricts or prevents the flow of that portion of gas.

As to Claim 2, Cutler discloses a flow combiner (the connection of conduits 38 and 21 to a common conduit (25). (Figure 3).

As to Claim 3, Cutler discloses the mixing chamber (32) has a serpentine pathway that varies over the course of the chamber. (Figure 3). Inherently, this pathway varies the size of the mixing chamber (32).

As to Claim 5, Cutler discloses the flow restrictor (30) is operated by the microprocessor (62). Inherently, this operation results in a variable restriction of flow.

As to Claim 7, Cutler discloses a port (33, as well as various other ports after the flow restrictor 30) though which the sample of gas may be removed from the mixing chamber (32), and used to sample gas within the mixing chamber (32). (Figure 3).

As to Claims 8 and 9, Cutler discloses the sensor (33) is connected to a monitoring device (16) in order to determine data from the mixing chamber (32). Regarding claim 9, Cutler discloses the sensor (33) is associated with temperature.

As to Claim 10, Cutler discloses the monitoring device (16) cooperatively works to determine the concentration of gases. (Figure 3 and Column 6, Lines 60-63).

As to Claim 11, Cutler discloses a display (15) connected to the monitoring device (16) for displaying the data form the sensor (33) via the microprocessor (62).

As to Claims 12 and 14, Cutler discloses the microprocessor (62) calculates the concentration of oxygen in the gaseous samples. (Column 6, Lines 60-63).

As to Claim 13, Cutler discloses the ability of the microprocessor (62) to cooperatively receive signals and change operation. (Column 7, Lines 8-20 and Column 7, Line 65 thru Column 8, Lines 11). Inherently, to be able to perform this function, the microprocessor (62) was programmed at fabrication. Further, Cutler discloses the sensors must be calibrated to set a base line of operation. Inherently this baseline would need to be stored in order to enable the device to operate at the new values separate from the default, thus constituting programming. (Column 7, Lines 30-65).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heinonen (6,196,222).

As to Claim 22, Heinonen discloses a ventilation circuit where the bypass mixer is on the inspiratory line, yet does not expressly disclose the connection of the bypass mixer to an expiratory line. However, at the time the invention was made the location of the bypass mixer from the inspiratory line to an expiratory line on a closed circuit system is a function of a change in location or rearrangement of parts. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made

to move the bypass mixer of Heinonen from a the inspiratory line to the expiratory line in a closed circuit system as disclosed in Figure 4 of Heinonen, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

12. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heinonen (6,196,222) in view of Feldman et al. (6,408,848).

As to Claim 4, Heinonen discloses a ventilation circuit where the bypass mixer, yet does not expressly disclose a portion of the mixing chamber to be made from a variable length tubing. However, at the time the invention was made the use of variable length tubing, such as corrugated tubing was known in the ventilation art. Specifically, Feldman teaches corrugated tubing was utilized for its ability to bend and retain shape in order to control the volumes of gases applied within the ventilation system. Thus, it would have been obvious to one having ordinary skill in the art to modify the ventilation tubing of Heinonen to include the corrugations as taught by Feldman for the purpose of controlling the volume of ventilation gas exposed within the system.

13. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cutler et al. (4,619,269) in view of Feldman et al. (6,408,848).

As to Claim 4, Heinonen discloses a ventilation circuit where the bypass mixer, yet does not expressly disclose a portion of the mixing chamber to be made from a variable length tubing. However, at the time the invention was made the use of variable

length tubing, such as corrugated tubing was known in the ventilation art. Specifically, Feldman teaches corrugated tubing was utilized for its ability to bend and retain shape in order to control the volumes of gases applied within the ventilation system. Thus, it would have been obvious to one having ordinary skill in the art to modify the ventilation tubing of Cutler to include the corrugations as taught by Feldman for the purpose of controlling the volume of ventilation gas exposed within the system.

14. Claims 9, 10, and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinonen (6,196,222) in view of Cutler et al. (4,619,269).

As to Claims 9 and 31, Heinonen discloses the use of a sensor for monitoring the operation of the bypass line, yet does not expressly disclose the use of a temperature sensor. However, at the time the invention was made the use of a temperature sensor was known. Specifically, Cutler discloses the temperature sensor (33) is connected to a monitoring device (16) in order to determine operational data from the mixing chamber (32). (Column 7, Lines 15-20). Therefore, it would have been obvious to one having ordinary skill in the art to modify the device of Heinonen to include a temperature sensor as taught by Cutler to provide a monitoring means to control the operation of the device.

As to Claims 10, 30, and 32, Heinonen discloses the use of a sensor for monitoring the operation of the bypass line, yet does not expressly disclose the monitoring of the concentration of gases. However, at the time the invention was made the monitoring of the concentration of gases was known. Specifically, Cutler discloses the monitoring device (16) cooperatively works to determine the concentration of gases

via the carbon dioxide sensor (48) and oxygen sensor (52). (Figure 3 and Column 6, Lines 60-63) for monitoring the ventilation of the patient (Abstract). Therefore, it would have been obvious to one having ordinary skill in the art to modify the device of Heinonen to include a sensor for monitoring the concentration of gases as taught by Cutler to provide a proper ventilation of the patient.

.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heinonen (6,196,222) in view of Winter et al. (5,555,880).

As to Claim 6, Heinonen discloses the use of flexible PVC tubing in the ventilation circuit (Column 6, Lines 1-4), yet Henionen does not expressly disclose the constructed of a rigid material. However, at the time the invention the construction of the plastic tube from a rigid material was known. Specifically, Winter teaches the construction of ventilation circuits to be flexible and made of a rigid or low compliance material for the purpose of minimizing the loss of volume delivered to the patient. (Column 3, Lines 43-45). Therefore, it would have been obvious to one having ordinary skill in the art to modify the ventilation circuit of Heinonen to be constructed with a rigid material for the purpose of minimizing the loss of volume delivered to the patient.

16. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heinonen (6,196,222) in view of Heinonen (5,967,141).

As to Claim 24, Heinonen ‘222 discloses a ventilation circuit, yet does not expressly disclose the application of anesthetic gas with the ventilation circuit.

However, at the time the invention was made the use of anesthetic gas with ventilation circuits was known. Specifically, Heinonen ‘141 teaches the application of anesthesia through the inspiratory line, for the purpose of anesthetizing the patient with the appropriate amount of medicament in relation to the inspiratory and expiratory flows of the patient. (Column 5, Lines 35-47). Thus, it would have been obvious to one having ordinary skill in the art to modify the system of Heinonen ‘222 to include an anesthetic gas as taught by Heinonen '141 to provide controlled and appropriate amounts of anesthetic to anesthetize the patient.

Allowable Subject Matter

17. Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Heinonen et al. (5,722,449), Aylsworth et al. (5,890,490), Goulding (5,072,737) Raemer et al. (4,211,239) Cox et al. (4,206,754), Olsoon et al. (5,423,313), Banner et al. (6,571,796), Jackson (3,592,191), Orr et al. (6,648,832), Atkins (5,239,994), Jones (5,605,148), Skog (6,298,848) disclose additional inventions with bypass lines wherein the gas flow is mixed prior to administration into the lungs of the patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon
Examiner
Art Unit 3771

/Annette F Dixon/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771